REMARKS

Claims 1-14 were pending at a mailing of the Non-Final Office Action dated March 28, 2008. All claims are amended. No new matter is introduced.

Priority

Applicant files with this reply a declaration for Utility Patent Application under 37 CFR §1.63, which acknowledges a filing of foreign applications.

Specification

The abstract of the disclosure is objected to because it is longer than 150 words. Applicant replaces that abstract with a compliant one. MPEP §608.01(b).

A withdrawal of the objection is respectfully requested.

Claim Rejections **- 35 USC § 112/101**

Claims 1-14 are rejected under 35 U.S.C. §112 because the method claims fail to set forth steps involved in a process. Applicant amends the Independent Claim and dependent claims to includes steps of a treatment process.

A withdrawal of the rejection is respectfully requested.

Claim Rejections **- 35 USC § 112**

Claims 1-14 are rejected under 35 U.S.C. §112, second paragraph, for failing to point out and distinctly claim subject matter.

Applicant amends every claim to overcome the various rejections based on lack of antecedent basis, lack of article, lack of clarity, etc.

A withdrawal of the rejection is respectfully requested.

Claim Rejections **- 35 USC § 102**

Claims 1 and 2 are rejected under 35 U.S.C. §102(b) as being anticipated by Ngan *et al. (Ann. NY Acad. Sci., 2001, 945, 73-79).*

Applicant amends a limitation from Claim 5 (cancelled) into Independent Claim 1. Applicant more specifically narrows the treatment agent used to destroy the extracellular DNA to a DNAse enzyme. Claims 1 and 2 are anticipated only if each and every element as set forth in the claim is found, either expressly described or inherently described, in Sammons. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Because this DNase enzyme is not taught nor suggested in the cited reference, it cannot be used to anticipate the claim.

A withdrawal of the rejection is respectfully requested.

Double Patenting Rejection

Claims 1-3 and 5 are provisionally rejected on a ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 in copending Application No. 10/564,609 to Anker.

Claims 1-3 and 5 are provisionally rejected on a ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 13 in copending Application No. 10/564,615.

Applicant files two terminal disclaimers with this reply.

Additional Remarks

Pilot clinical trials of DNAse enzyme monotherapy in patients with advanced cancer of different origin have been performed. The trials were performed in St.Petersburg at the St.Petersburg Academy of Advanced Medical Education; Department of Thoracal Surgery. Totally 12 patients were included according to following inclusion criteria:

- Men and women 18 y. or older
- T4M+ advanced cancer of any orign
- Diagnosis proved by clinical, instrumental and laboratory assessment
- Absence of any alternative treatment modality
- CT(Spiral Computer Tomography) or clinical evidence of rapidly progressing disease
- Karnofsky performance score >40

The following patients were included:

- MOI - Malignant Melanoma. Multiple lung and liver metastasis.
- GEF- Breast cancer. Disseminated bone metastasis.
- FVV-Breast cancer. Disseminated lung and liver metastasis.
- KNP- Gastric cancer. Disseminated lymphatic and liver metastasis.
- PGP-Colon cancer. Disseminated lung and liver metastasis.
- MCF-Colon cancer. Local reappearance. Disseminated lymphatic and liver metastasis.
- MVI-Pancreatic adenocarcinoma. Disseminated lymphatic metastasis.
- SSA- Lung cancer. Disseminated lung and lymphatic metastasis.
- ISP- Colon cancer. Liver metastasis.
- BVI- Recurrent Renal cancer. Multiply bone metastasis.
- CLV- Recurrent rectal carcinoma. Multiply bone and lung metastasis.
- BAI- Lung cancer. Disseminated lung and lymphatic metastasis

The patients received one course of monotherapy with bovine pancreatic DNAse enzyme according following regimen:

- Treatment duration -21 day.
- DNAse delivery-20 min. intravenous infusion in isotonic sodium chloride.
- Number of daily infusions - 6.

- Day 1-8: 50 mg per infusion (510 000 Kunitz units per day)
- Day 8-12: 75 mg per infusion (765 000 Kunitz units per day)
- Day 12-21: 100 mg per infusion (1 020 000 Kunitz units per day)

The efficacy was assessed on day 30 after start of therapy. All patients demonstrated stabilization of the disease. (Spiral CT scan; RECIST criteria). All patients demonstrated significant increase in Karnofsky performance score; some patients show shrinkage of metastatic nodules.

The conclusion drawn from these trials is that DNAse therapy is effective in treatment of malignant tumors of different origin.

CONCLUSION

In view of the amendments submitted herein and the above comments, it is believed that all the grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Should there be any further questions, Examiner is urged to telephone Applicant's undersigned attorney at (330) 253-2225

Respectfully submitted,

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